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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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10/24/00

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/132,156

Applicant(s)
Wittwer et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/9/01 re Exr. Int. Sum.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-89 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s) 18 x 19
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other Attachment for PTO-948

Applicants' arguments, filed 1/22/01, and a reconsideration of the Exr. Interview of 7/9/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The mailing of this office action restarts the response time that was originally set in the office action, mailed 4/24/01.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 3 on 3/30/99. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed alterations have been made to the oath or declaration (see 37 C.F.R. §§ 1.52(c) and 1.57).

Claims 59-89 are rejected, as discussed below, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amplification reactions performed in a capillary vessel or hollow elongate glass tubes, does not reasonably provide enablement for any generic reaction vessels or sample holding structure. Applicants have argued that the sample holder must be of low thermal mass, of which a capillary tube is an preferred embodiment only. Thus, some characteristic of the sample holder must permit rapid thermal cycling. Applicants have persuasively argued that any container will not do. Therefore, some limitation as to the sample holder which permits rapid thermal cycling is admitted by applicants. As presently worded the instant claims do not limit the sample container at all other than it holds sample. This scope is broader than the clear need for sample containers which function similar, at least, to a capillary for rapid heat transfer. This is supported as previously stated by Wittwer et al.(1991) and Swerdlow et al.(1993) and has not been disagreed with in applicants arguments. In the Examiner Interview of 7/9/01 the above rejection was discussed and agreed to be withdrawn. Upon reconsideration, the above rejection contains reasoning that indicates that applicants' sample holder must indeed have some

limitations regarding thermal conductivity etc. in order to achieve rapid cycle times. Such sample holder limitations are summarized above and there is no written description that enables some generic holder beyond some limitation as set forth above. Thus, regrettably this rejection is hereby maintained. If applicants wish to submit evidence as to what was known in the art for rapid PCR temperature cycling at the time of the instant invention these would be considered as to what additional generic sample holder types were well known and/or conceived by the inventors.

Claims 59-80 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "about 30-60 second" in claims 59 and 70 causes these claims and claims dependent therefrom because it is vague and indefinite as to whether the "about" limitation applies only to the lower 30 second time or both the 30 and 60 second time periods. Clarification via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed

publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 59, 60, 62, 64-68, 70, 71, 74-79, 81, 83-86, and 88 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Larzul (P/N 5,176,203).

Larzul discloses an apparatus and method of use thereof wherein a rapid PCR method is performed as summarized in the abstract. The sample holder is a capillary tubing which would be well known to maximize heat transfer due to its capillary nature. Rapid thermal cycling in the range of 1-5 minutes per cycle or stage is disclosed in column 3, lines 18-20, which is deemed to be within the range of the instant claims directed to such a cycle of "about 30-60 seconds" as given in instant claim 59. It is additionally noted that the instant claims indicate the contacting of heated or non-heated fluid to the sample holder as is also disclosed in the reference in column 3, lines 52-63, wherein various heating media are disclosed specifically including fluids such as liquid or gaseous types. These disclosure anticipate the above listed instant claims. A review of the parent applications/patents related to the instant

application has failed to reveal written basis for the various rapid cycling times in the instant claims as filed within one year after the Larzul Patent filing and issue date.

No claim is allowed.

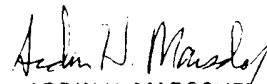
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 18, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.